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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,251	10/29/2004	Masayuki Machida	Q82106	8931

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
LEE, JAE W	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,251	MACHIDA ET AL.	
	Examiner	Art Unit	
	Jae W. Lee, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1,4-6,15-24,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,7-14 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/23/2004, 07/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

Claim(s) 1-27 is/are pending in this application.

Priority

A claim of priority to applications, PCT/JP02/13627, filed on 12/26/2002, and JAPAN 2001-403261, filed on 12/27/2001, is acknowledged.

Election

Applicant's election of Group II, Claims 2-14, 24 and 25 and SEQ ID NO: 5, in the response filed on 11/29/2006 and 09/24/2007, respectively, is acknowledged.

Claims 2, 3, 7-14 and 25 will be examined on the merits.

Claim(s) 1, 4-6, 15-24, 26 and 27 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Objections to the Specification

The specification is objected to for inappropriate notation of an Internet address. On pg. 39 under Example 2, 2nd paragraph, Internet address is cited in an unacceptable form because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See also M.P.E.P. 707.05(e) for the acceptable notation of an Internet address. The examiner suggests the replacement of Internet citations with appropriate references because Internet pages are subjected to frequent changes and deletions and could be different when the public accesses the Internet page to view the exactly same information.

Appropriate correction is required.

Claim Objections

Claim(s) 2, 3, 7-14 and 25 is/are objected to because of the following informalities:

Claims 2 (7-14 and 25 dependent therefrom) are objected to because it depends from a non-elected claim 1.

Claims 3 and 25 are objected to because they contain non-elected subject matter, i.e., SEQ ID NO: 1.

Claim 7 is objected to because it depends from non-elected claims 4 and 5.

Claim 8 is objected to for containing a grammatical error in a phrase, "Claims 2 or 3." In the interest of advancing prosecution, said phrase is interpreted to be "Claim 2 or 3."

Claim 11 is objected to for the recitation of "comprising DNA comprising a nucleotide sequence," which is redundant.

Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 3, and 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed product, as written, does not sufficiently distinguish over the naturally occurring product in living organism, i.e., DNA sequence from *Aspergillus oryzae* as set forth in SEQ ID NO: 5. The claims do not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of "the hand of man", the naturally occurring products are

considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206, USPQ 193 (1980) and M.P.E.P. 2105.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7-9 and 25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 25 (7-9 dependent therefrom) are indefinite in the recitation of "hybridizing" as this term is unclear absent a statement of the conditions under which the hybridization reaction is performed. Nucleic acids which will hybridize under some hybridization conditions will not necessarily hybridize under different conditions.

Claims 3 and 25 (7-9 dependent therefrom) are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent". While paragraph [0024] of the specification describes some conditions which are intended to be stringent, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination. As such it is unclear

how homologous to the nucleotide sequence of SEQ ID NO: 5, a sequence must be to be included within the scope of these claims.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 7-14 and 25 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to [1] a genus of DNA comprising a nucleotide sequence encoding a polypeptide selected from the group consisting of the following (a) to (c): (a) a polypeptide comprising an amino acid sequence shown in SEQ ID NO: 2, (b) a polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2, and having a pyroglutamyl peptidase activity, and (c) a polypeptide comprising an amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2, and having a pyroglutamyl peptidase activity; or [2] a genus of DNA selected from the

group consisting of the following (b) to (c): (b) DNA comprising a nucleotide sequence shown in SEQ ID NO: 5, and (c) DNA which hybridizes with DNA comprising a nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, [3] a genus of transformants comprising said genus of DNAs, and [4] a genus of processes for producing any polypeptide encoded by said genus of DNAs.

To satisfy the written description aspect of 35 U.S.C. § 112, first paragraph, for a claimed genus of [compositions or methods], it must be clear that: (1) the identifying characteristics of the claimed [compositions or methods] have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed.

The specification discloses only a single representative species of an isolated DNA sequence from *Aspergillus oryzae* as set forth in SEQ ID NO: 5, which encodes the pyroglutamyl peptidase. However, this single disclosed species fails to provide adequate written description for a genus of DNAs comprising [1] any nucleotide sequence encoding any polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2 and having a pyroglutamyl peptidase activity; [2] any nucleotide sequence encoding a polypeptide comprising any amino acid sequence wherein

one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2; [3] any DNA that hybridizes with DNA comprising any nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, optionally having any DNA sequences attached to N- and/or C-terminal ends; [4] a genus of transformants comprising said genus of DNAs, and [5] a genus of processes for producing any polypeptide encoded by said genus of DNAs.

In this case, the specification fails to describe any identification of structural characteristics or properties of a genus of DNAs comprising [1] any nucleotide sequence encoding any polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2 and having a pyroglutamyl peptidase activity; [2] any nucleotide sequence encoding a polypeptide comprising any amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2; and [3] any DNA that hybridizes with DNA comprising any nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, optionally having any DNA sequences attached to N- and/or C-terminal ends. Taken together, the genus of "DNAs" encompasses widely variant species, having essentially any structure. While M.P.E.P. section 2163 acknowledges

that a single species can describe a genus, it also acknowledges that for a genus that encompasses widely variant species, disclosure of a single species within the genus fails to adequately describe all members of the genus. Please refer to the M.P.E.P. section 2163 [R-5] under II, A, 3, (a), (ii) for more details with respect to sufficient number of representative species that should be disclosed to describe a widely variant genus.

Given the lack of additional representative species of a genus of DNAs comprising [1] any nucleotide sequence encoding any polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2 and having a pyroglutamyl peptidase activity; [2] any nucleotide sequence encoding a polypeptide comprising any amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2; and [3] any DNA that hybridizes with DNA comprising any nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, optionally having any DNA sequences attached to N- and/or C-terminal ends as encompassed by the claim, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 2, 3, 7-14 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for an isolated DNA sequence from *Aspergillus oryzae* as set forth in SEQ ID NO: 5, which encodes the pyroglutamyl peptidase, does not reasonably provide enablement for any DNA comprising [1] any nucleotide sequence encoding any polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2 and having a pyroglutamyl peptidase activity; [2] any nucleotide sequence encoding a polypeptide comprising any amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2; [3] any DNA that hybridizes with DNA comprising any nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, optionally having any DNA sequences attached to N- and/or C-terminal ends; [4] a genus of transformants comprising said genus of DNAs, and [5] a genus of processes for producing any polypeptide encoded by said genus of DNAs as encompassed by the claims. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

Claims 2, 3, 7-14 and 25 are so broad as to encompass any DNA comprising [1] any nucleotide sequence encoding any polypeptide comprising an

amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2 and having a pyroglutamyl peptidase activity; [2] any nucleotide sequence encoding a polypeptide comprising any amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2; [3] any DNA that hybridizes with DNA comprising any nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, optionally having any DNA sequences attached to N- and/or C-terminal ends; [4] a genus of transformants comprising said genus of DNAs, and [5] a genus of processes for producing any polypeptide encoded by said genus of DNAs.

The specification discloses an isolated DNA sequence from *Aspergillus oryzae* as set forth in SEQ ID NO: 5, which encodes the pyroglutamyl peptidase. With regard to the use of all "DNAs" that encode all possible mutants and fragments of pyroglutamyl peptidase having the amino acid sequence of SEQ ID NO: 5, it is noted by the Examiner that not all structurally different pyroglutamyl peptidase mutants would be able to catalyze the release of a N-terminal pyroglutamyl group from a polypeptide provided the next residue is not proline. Therefore, the disclosure of an isolated DNA sequence from *Aspergillus oryzae* as set forth in SEQ ID NO: 5, which encode the pyroglutamyl peptidase capable of catalyzing the release of a N-terminal pyroglutamyl group from a polypeptide

provided the next residue is not praline, does not commensurate with the breadth of claimed inventions encompassing the use of all possible "DNAs."

The claims rejected under this section of U.S.C. 112, first paragraph, do not place any structural limits on the "DNA." Since the nucleic acid/amino acid sequence of a peptide determines its structural and functional properties, predictability of which nucleotides/peptides can be used while obtaining the desired function requires a knowledge of and guidance with regard to which nucleic acids encoding amino acids in the peptide's sequence, if any, are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the peptide's structure relates to its desired function. In addition, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of different nucleotides.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within nucleotide encoding a protein where nucleic acid/amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any nucleotide encoding a protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA because the specification does not establish: (A) regions of any DNA structure which may be modified without affecting the desired biological activity of the encoded protein, i.e., the release of a N-terminal pyroglutamyl group from a polypeptide; (B) the general tolerance of any DNA to modification and extent of such tolerance without affecting the desired biological activity of the encoded protein, i.e., the release of a N-terminal pyroglutamyl group from a polypeptide; (C) a rational and predictable scheme for modifying any nucleic acid residue of any DNA with an expectation of obtaining the desired activity/utility; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Because of this lack of guidance, and the fact that the relationship between the polynucleotide encoding a protein and its activity/function is not well understood and unpredictable (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, Ref: U, Form-892), it would require undue experimentation for one skilled in the art to make and use the claimed inventions.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of any DNA comprising [1] any nucleotide sequence encoding any polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2 and having a

pyroglutamyl peptidase activity; [2] any nucleotide sequence encoding a polypeptide comprising any amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2; [3] any DNA that hybridizes with DNA comprising any nucleotide sequence complementary to the nucleotide sequence shown in SEQ ID NO: 5 under stringent conditions, and comprises a nucleotide sequence encoding a polypeptide having a pyroglutamyl peptidase activity, optionally having any DNA sequences attached to N- and/or C-terminal ends; [4] a genus of transformants comprising said genus of DNAs, and [5] a genus of processes for producing any polypeptide encoded by said genus of DNAs having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 8-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Awade et al. (Federation of European Biochemical Societies, 1992, 305(1): 67-73), in view of the evidentiary reference from MeSH database, <URL:http://www.ncbi.nlm.nih.gov/sites/entrez?Db=mesh&Cmd=ShowDetailView&TermToSearch=68011751&ordinalpos=1&itool=EntrezSystem2.PEntrez.Mesh.Mesh_ResultsPanel.Mesh_RVDocSum>.

The instant claims are drawn to DNA comprising a nucleotide sequence encoding a polypeptide selected from the group consisting of the following (a) to (c): (a) a polypeptide comprising an amino acid sequence shown in SEQ ID NO: 2, (b) a polypeptide comprising an amino acid sequence substantially identical to the amino acid sequence shown in SEQ ID NO: 2, and having a pyroglutamyl peptidase activity, and (c) a polypeptide comprising an amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2, and having a pyroglutamyl peptidase activity.

The reference of Awade et al. teach the characterization of *pcp* gene from *Bacillus subtilis* encoding a pyrrolidone carboxyl peptidease, also known as pyroglutamyl peptidase, which anticipate the limitation of claim 2, in the recitation of "a nucleotide sequence encoding a polypeptide selected from the group consisting of the following (a) to (c): (c) a polypeptide comprising an amino acid sequence wherein one or more amino acid residues are deleted, substituted or added in the amino acid sequence shown in SEQ ID NO: 2, and having a

pyroglutamyl peptidase activity." It is noted by the Examiner that according to MeSH database, "Pyroglutamyl-Peptidase" is synonymously used with pyrrolidonecarboxylate peptidease (see below and also http://www.ncbi.nlm.nih.gov/sites/entrez?Db=mesh&Cmd=ShowDetailView&TermToSearch=68011751&ordinalpos=1&itool=EntrezSystem2.PEntrez.Mesh.Mesh_ResultsPanel.Mesh_RVDocSum).

Claim 8 is included in this rejection because said reference teaches the recombinant DNA of *pcp* gene (see under Materials and Methods).

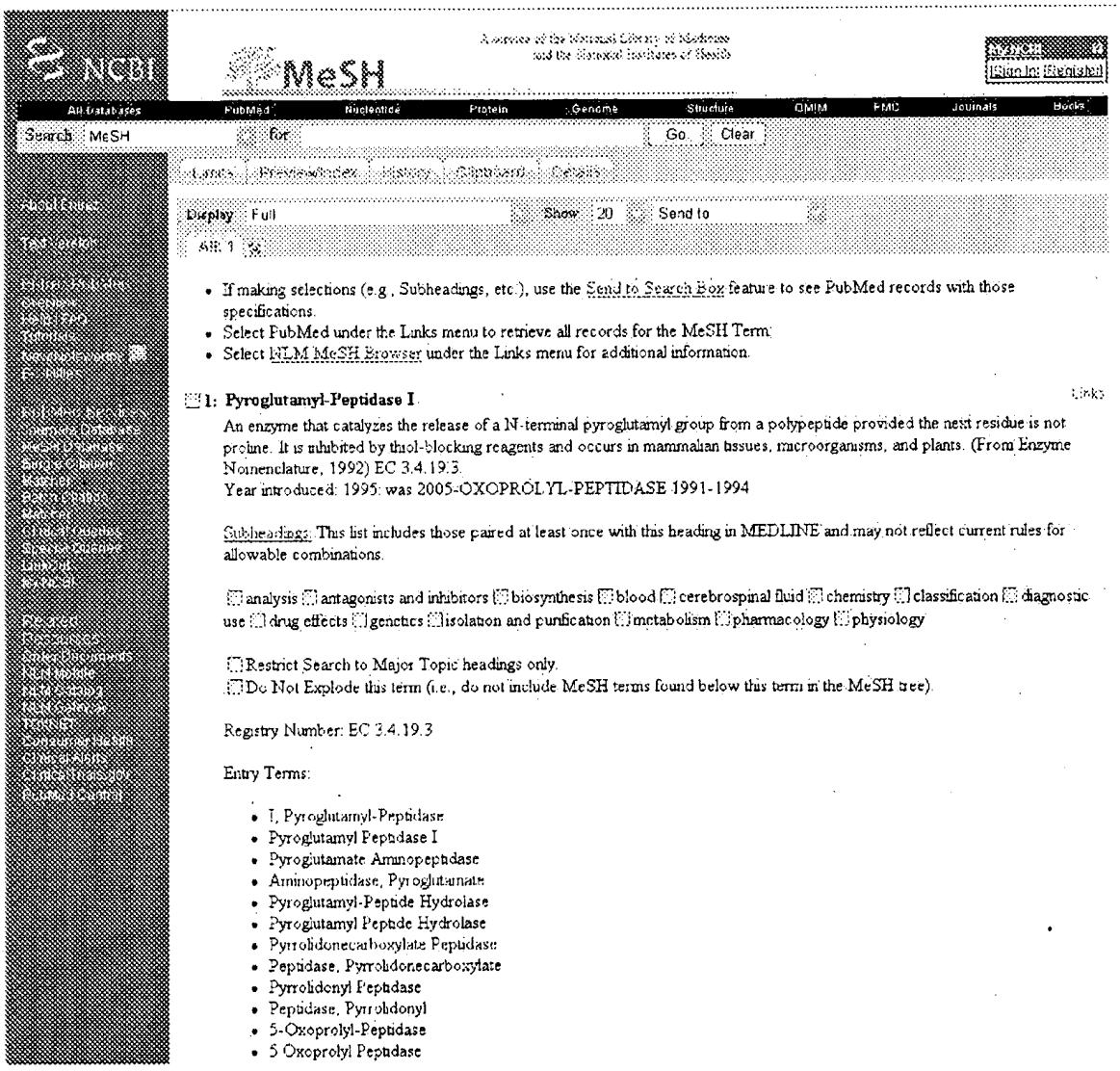
Claim 9 is included in this rejection because said reference teaches the use of *E. coli* as a transformant with an expression plasmid vector containing the *pcp* gene in order to express the Pcp protein (see under Materials and Methods).

Claim 10 is included in this rejection because said reference teaches a process for the expression and isolation of the Pcp protein, comprising culturing said *E. coli* in a LB medium (see under Materials and Methods).

Claim 11 is included in this rejection because said reference teaches said process comprises the *E. coli* having an expression plasmid vector containing the *pcp* gene in order to express the Pcp protein, which anticipate the limitation of claim 11, in the recitation of "[t]he process according to claim 10, wherein the microorganism is a transformant comprising a recombinant DNA comprising DNA comprising a nucleotide sequence encoding ... (c) a polypeptide comprising an amino acid sequence wherein one or more amino acid residues are deleted,

substituted or added in the amino acid sequence shown in SEQ ID NO: 2, and having a pyroglutamyl peptidase activity."

Therefore, the reference of Awade et al. anticipates Applicants' Claims 2 and 8-11.



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All: 1

- If making selections (e.g., Subheadings, etc.), use the Send to Search Box feature to see PubMed records with those specifications.
- Select PubMed under the Links menu to retrieve all records for the MeSH Term.
- Select NLM MeSH Browser under the Links menu for additional information.

1: **Pyroglutamyl-Peptidase I**

Links

An enzyme that catalyzes the release of a N-terminal pyroglutamyl group from a polypeptide provided the next residue is not proline. It is inhibited by thiol-blocking reagents and occurs in mammalian tissues, microorganisms, and plants. (From Enzyme Nomenclature, 1992) EC 3.4.19.3.
Year introduced: 1995; was 2005-OXOPROLYL-PEPTIDASE 1991-1994

Subheadings: This list includes those paired at least once with this heading in MEDLINE and may not reflect current rules for allowable combinations.

analysis | antagonists and inhibitors | biosynthesis | blood | cerebrospinal fluid | chemistry | classification | diagnostic use | drug effects | genetics | isolation and purification | metabolism | pharmacology | physiology

Restrict Search to Major Topic headings only.
Do Not Explode this term (i.e., do not include MeSH terms found below this term in the MeSH tree).

Registry Number: EC 3.4.19.3

Entry Terms:

- L, Pyroglutamyl-Peptidase
- Pyroglutamyl Peptidase I
- Pyroglutamate Aminopeptidase
- Aminopeptidase, Pyroglutamate
- Pyroglutamyl-Peptide Hydrolase
- Pyroglutamyl Peptide Hydrolase
- Pyrrolidonecarboxylate Peptidase
- Peptidase, Pyrrolidonecarboxylate
- Pyrrolidonyl Peptidase
- Peptidase, Pyrrolidonyl
- 5-Oxoprolyl-Peptidase
- 5 Oxoprolyl Peptidase

Conclusion

Claims 2, 3, 7-14 and 25 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

The instant Office action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Jae W. Lee, Ph.D.

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER